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09/900,278	07/06/2001	Magdy A. Eletreby	CRNI.134923	8634

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EXAMINER	
SEREBOFF, NEAL	

ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/900,278	ELETREBY ET AL.	
	Examiner	Art Unit	
	NEAL R. SEREBOFF	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Amendment

1. In the amendment filed 5/29/07, the following has occurred: claims 49 and 54 have been amended and claim 62 has been added. Now, claims 49-62 are presented for examination.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

3. ***Claims 49-57 and 59-62*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Schrier et al., U.S. Patent No. 6,317,719 in view of Bloom et al., U.S. Patent No. 6,070,761 and further in view of Akers et al., U.S. Patent No. 6,112,182.

4. As per claim 49, Schrier teaches a method of managing the pharmaceutical care of a patent using one or more software-accessible databases comprising the steps of: updating a patient database with a drug therapy regimen for the patient, the drug therapy regimen comprising an identification of each drug prescribed to the patient, a frequency per day for each drug, and a daily dosage for each drug (see column 14, lines 15-20); updating the patient database with patient data, the patient data comprising any disease states and allergies for the patient (see column 6, lines 4-11); querying a clinical database with the drug therapy regimen and patient data, wherein the querying step further comprises identifying: (a) allergies the patient has for any of the prescribed drugs (see column 3, lines 39-46); (b) drug-drug interactions for any of the prescribed drugs (see column 3, lines 39-46); (c) dosage irregularities (see column 3, lines 39-46); (d) drug-disease contraindications (see column 3, lines 39-46); (g) adverse drug reactions (see column 3, lines 39-46); and (h) untreated disease states (see column 8, lines 36-40); querying the clinical database with a selection, by a clinician, of a disease state from a list of

one or more existing disease states associated with the patient (see column 8, lines 36-51); and presenting a user with one or more alternative drugs based at least in part on the querying step (see column 11, lines 30-44); and generating a report based on one of the querying steps (see column 3, lines 41-48).

5. Schrier does not explicitly teach identifying therapeutic duplications or drugs in the drug therapy regimen without a medical indication. Bloom teaches an automated medication management system that includes the functions of identifying therapeutic duplications and drugs in the drug therapy regimen without a medical indication (see column 11, lines 10-33). It would have been obvious to one of ordinary skill in the art at the time of the invention to add such functionality to the existing drug-patient analysis element of Schrier. One of ordinary skill in the art would have been motivated to add such functionality for the purpose of enhancing relevant knowledge provided to physicians for making treatment determinations (see column 1, lines 51-54 of Schrier).

6. Schrier also does not explicitly teach that each drug in the clinical database is associated with a multi-character therapeutic cross reference code, wherein a first set of characters represent a class of drugs, a second set of characters represents a subclass of drugs, and a third set of characters represent a specific drug, and wherein the identification is based in part on a comparison of the multi-character therapeutic cross reference code with the patient database records. However, Akers teaches an integrated healthcare management system which maintains a clinical database of drugs that each are associated with a multi-character therapeutic cross reference code, wherein a first set of characters represent a class of drugs, a second set of characters represents a subclass of drugs, and a third set of characters represent a specific drug

(see column 5, lines 18-21 and Figure 4, the Examiner is interpreting the "generic class" to be a form of "class of drugs," the "therapeutic class" to be a form of "subclass of drugs," and the "drug name or NDC" to be form of "specific drug"). Akers further teaches identifying certain "triggers" by a comparison of the multi-character therapeutic cross reference code with the patient database records (see column 5, lines 1-6 and Figure 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such coding features with the combined teachings of Schrier and Bloom. One of ordinary skill in the art would have been motivated to combine such a feature as this for the purpose of better providing appropriate information and delivery of healthcare services (see column 2, lines 12-24 of Akers).

7. As per claim 50, Schrier in view of Bloom and Akers teach the method of claim 49 as described above. Schrier further teaches the querying step identifies the following additional information for each patient: (i) information regarding use or efficacy of any of the prescribed drugs (see column 3, lines 46-48); and (j) information regarding patient compliance (see column 6, lines 4-10).

8. As per claim 51, Schrier in view of Bloom and Akers teach the method of claim 50 as described above. Schrier further teaches the querying step identifies the following additional information for each patient: (k) information regarding an assessment of the educational needs of the patient (see column 6, lines 33-35, the Examiner considers patient age to be indicative of educational needs); (l) information regarding the financial circumstances of the patient (see column 10, lines 45-48).

9. As per claim 52, Schrier in view of Bloom and Akers teach the method of claim 49 as described above. Schrier further teaches the drug therapy regimen for the patient comprises a

plurality of drugs prescribed by more than one physician (see column 7, line 56 – column 8, line 3).

10. As per claim 53, Schrier in view of Bloom and Akers teach the method of claim 49 as described above. Schrier further teaches the clinical database is queried with the one or more alternative drugs prior to presentation to the user (see column 11, lines 44-47).

11. Claims 54 and 57 recite substantially similar limitations to those already addressed in claim 49 and, as such, are rejected for similar reasons as given above.

12. As per claim 55, Schrier in view of Bloom and Akers teach the method of claim 54 as described above. Although the combination of Schrier in view of Bloom and Akers does not explicitly teach that the multi-character therapeutic cross reference code comprises an eight character code with the class, subclass, and specific drug represented as two, four, and two characters respectively, these differences are only found in the non-functional data that labels the class, subclass, and specific drug indicated by the multi-character therapeutic cross reference code. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, *see Cf. In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to choose any number of characters to represent the class, subclass, and specific drug because merely labeling the data differently from that in the prior art would have been obvious matter of design choice. *See In re Kuhle*, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975).

13. As per claim 56, Schrier in view of Bloom and Akers teach the method of claim 54 as described above. Schrier does not explicitly teach the multi-character cross reference code is

associated with drug indications and contra-indications via ICD-9 codes. However, Akers further teaches the multi-character cross reference code is associated with drug indications and contra-indications via ICD-9 codes (see column 6, lines 32-36). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such coding features with the combined teachings of Schrier and Bloom for the reasons given above with respect to claim 49.

14. As per claim 59, Schrier in view of Bloom and Akers teach the method of claim 54 as described above. Schrier further teaches the drug therapy regimen data is automatically imported from a pharmacy dispensing system (see column 13, lines 38—53).

15. Claims 60 and 62 recite substantially similar limitations to those already addressed in claim 49 and, as such, is rejected for similar reasons as given above.

16. As per claim 61, Schrier in view of Bloom and Akers teach the method of claim 60 as described above. Schrier does not explicitly teach the identifying step highlights a particular drug in a patient's current drug regimen in addition to listing other drugs in the class or subclass with the same adverse reaction. Akers further teaches highlighting a particular drug in a patient's current drug regimen in addition to listing other drugs in the class or subclass with the same adverse reaction (see column 4, line 49 – column 5, line 9). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature with the combined teachings of Schrier and Bloom for the reasons given above with respect to claim 49.

17. ***Claims 58*** is rejected under 35 U.S.C. 103(a) as being unpatentable over Schrier et al., U.S. Patent No. 6,317,719 in view of Bloom et al., U.S. Patent No. 6,070,761 and Akers et al., U.S. Patent No. 6,112,182 and further in view of Mayaud, U.S. Patent No. 5,845,255.

18. As per claim 58, Schrier in view of Bloom and Akers teaches the method of claim 54 as described above. Schrier does not explicitly teach generating a compliance percentage. Mayaud teaches a system for managing drug therapy regimen data and generating a compliance percentage (see column 28, lines 30-37, the Examiner notes that the recited formula equates to an amount of drug actually taken versus an amount prescribed which is what is reported on in Mayaud). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the system of Schrier. One of ordinary skill in the art would have been motivated to incorporate such a feature for the purpose of enhancing the ready access to current, patient-specific drug information, as identified as an object of Schrier (see column 3, lines 36-59).

Response to Arguments

19. Applicant's arguments, see 35 U.S.C. 112, 2nd paragraph rejections, filed 1/8/2008, with respect to claims 49 – 59 have been fully considered and are persuasive. The 35 U.S.C. 112, 2nd paragraph rejection of claims 49 – 59 has been withdrawn.

20. Applicant's arguments filed 1/8/2008 have been fully considered but they are not persuasive.

- Regarding independent claims 1 and 54,

- The Applicant states on page 9 of his response that the "Schrier reference fails to teach or suggest a method of managing care in which the *clinician manages* a condition having knowledge and context of a number of other conditions." (emphasis added) The Examiner notes the claims do not require or state who manages the conditions.
- The Applicant continues, "But the Schrier reference does not teach or suggest presenting the clinician with a list of one or more disease states and querying the clinical database with a selection of a disease state, thus presenting the clinician with knowledge of various other patient conditions." The Examiner further notes that these limitation are also not claimed.
    - However, if this were claimed,
        - Schrier states, column 2, lines 44 - 55, that:

"In general, in another aspect, the invention features a method for processing data relating to use of an index drug by a patient, which includes receiving the identity of the index drug and information about the patient and determining a dosage of the index drug on the basis of the information about the patient. Further embodiments of the invention so include the following features. Receiving information about the patient selected from the patient's age, height, weight, sex, kidney function, liver function, and the clinical condition for which the index drug would be used, searching data files for records pertaining to the index drug and building a message with information derived from the records."

- Schrier states, column 1, lines 51 - 55, that:

"Thus, there is a need for systems and methods capable of providing the clinician with ready and convenient access to current, pertinent, and patient-specific drug information and dosing recommendations."

- The Examiner notes that the paragraph on page 10 regards a database and searching the respective database. The Applicant states that Schrier "may require

information about the patient's clinical condition from the clinician." The Examiner reminds the Applicant that claim 1 includes, "updating the patient database with patient data, the patient data comprising any disease states and allergies for the patient." Therefore, the Examiner is confused by the argument that Schrier is different when the claim requires the same steps Schrier has. Once the patient information is entered, Schrier, as the claim, then queries the database. (Schrier, column 8, lines 52 – 67).

- Regarding independent claim 60, the Applicant claims that Schrier does not teach a "query based on a given adverse reaction." The Applicant further notes that "the portion of the Schrier reference cited by the Examiner as meeting this limitation is yet another example of the patient-centric nature of the Schrier reference." The Examiner notes that the Applicant's Figure 9 shows 2 different methods of querying the database for adverse reactions with question "Patient selected?" (#915) leading to the two different approaches. As Claim 60 does not require the adverse reaction query be done independently of a patient, the Schrier reference is applicable.
    - Although not currently claimed, the Schrier reference allows for further searching independently of a particular patient. (Schrier, column 33, lines 17 - 39).
- Regarding independent claim 62, the Applicant claims that Schrier does not teach "querying the clinical database with a drug class or a drug subclass." The Detailed Description, page 10, line 11, states that the "the clinical data classifies drugs into therapeutic classes, and for each class there is associated therewith known indications,

contra-indications, recommended dosages, known adverse reactions, and drug interactions."

- The Examiner notes that the Schrier drug database includes these therapeutic classes or therapeutic categories as described in Schrier, column 5, lines 53 – 67.
  - The selected area includes, "If the user has selected a category, the drugs displayed in the left-hand list are only those drugs in the selected category (including all depths of subcategories) and the right-hand category list then contains only the subcategories of the selected category, which the user may then select from, as long as there are subcategories to select."
- Therefore the Schrier reference does teach drug class and subclass queries.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEAL R. SEREBOFF whose telephone number is (571)270-1373. The examiner can normally be reached on Mon thru Thur from 7:30am to 5pm, with 1st Fri off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. S./
Examiner, Art Unit 3626
3/13/2008

/Robert Morgan/
Primary Examiner, Art Unit 3626